PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Ethicus II - Germany (The End-of-life practices in intensive units around the world study / Germany)

Trial Acronym

Ethicus II - D

URL of the trial

[---]*

Brief Summary in Lay Language

Ethicus II - Germany will assess current EOL practices in Germany as part of a larger, international study (Ethicus II) which assesses current practices in ICUs throughout the world.
Fifteen years ago, the European-wide Ethicus study [1] showed that up to 20% of patients die in the ICU, mostly after decisions to limit the intensity of life-sustaining treatments. However, end-of-life decisions and practices varied considerably around Europe . Now, we want to compare how practices have changed in those ICUs that participated in the initial ETHICUS study and in other countries around the world. In the German centers we will carry out additional surveys to evaluate the perception and well-being of the patients' relatives as well as the treating ICU physicians and nurses to determine risk factors for end-of-life decisions as well as their impact on relatives and staff

Brief Summary in Scientific Language

Although intensive care units (ICUs) save lives, up to 20% of patients die in the ICU. Most ICU deaths occur after decisions to limit the intensity of life-sustaining treatments. Such decisions affect the patients' relatives, who bear the burden of losing a loved one and having to fulfill the duties of proxies during decision-making. Up to 30 to 50% of relatives suffer from symptoms of anxiety, depression and posttraumatic stress as long as 3 months afterwards [2,3]. Decision-making also affects ICU medical staff. End-of-life care is stressful for nurses and physicians who also have different roles and responsibilities [4,5]. Poor work environment may increase job-related strain and impair staff wellbeing [5,6,7]. Fifteen years ago, the initial Ethicus study showed that end-of-life decisions and practices varied considerably around the world.

With the Ethicus II study – a prospective, observational study - we want to compare how practices are now and whether they have changed in those ICUs that participated in the initial ETHICUS study. All patients who die or who had a limitation of life-sustaining interventions in the ICU will be included. The total number of patients admitted to each ICU during the study period will be collected

to ascertain the frequency of end-of-life decisions. All patients will be enrolled into the study anonymously only after IRB approval. Five mutually exclusive categories are defined: Failed cardiopulmonary resuscitation (CPR, i.e. death despite ventilation and cardiac massage); Brain death (i.e. documented cessation of cerebral function and meeting criteria for brain death); Withholding (WH) treatments (i.e. a decision was made not to start or increase a life-sustaining intervention. Decision to not perform CPR (do-not-resuscitate) is classified as withholding therapy); Withdrawing (WD) treatments (i.e. a decision was made to actively stop a life-sustaining intervention presently being given) and Active Shortening of the Dying Process (SDP) which is defined as a circumstance in which someone performed an act with the specific intent of shortening the dying process. In addition, the German centers will also perform a survey among relatives after 3 months to assess their perception and satisfaction with decision-making and care as well as psychological symptoms. A survey will also be conducted among treating ICU physicians and nurses to measure their perception of work environment and their psychological wellbeing. Lastly, a culture-specific survey of the structure of participating ICUs will be performed to assess differences.

Study population- All consecutive adult patients admitted to the ICU who die or have any limitation of life-saving interventions in the ICU for the 6 month study period will be studied prospectively. In the event of end-of-life decisions, characteristics of decision-making will be ascertained from the decision-making physician. Patients will be followed until discharge from ICU, hospital, death, or 2 months from the decision to limit therapy. Main relatives of included patients are included if the patient stayed for longer than 48 hours in the ICU. All ICU nurses and physicians involved in the care of patients are eligible.

Organizational Data

- DRKS-ID: **DRKS00010044**
- Date of Registration in DRKS: **2016/02/12**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **4311-01/15 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

Secondary IDs

Health condition or Problem studied

- Free text: • **Intensive Care**
  • **Dying in the intensive care unit**
  • **Limitation of life-sustaining treatment in the ICU**

Interventions/Observational Groups

- Arm 1: **All consecutive adult patients admitted to the ICU who die or have any limitation of life-saving interventions in the ICU are observed; all relatives are invited to participate in a postal survey after 90 days; all physicians and nurses in the ICU are questionned once with a staff survey .**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Health care system**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

• end of life category

Secondary Outcome

• characteristics of decision-making
• time periods between admission and death/discharge or until end-of-life decision, time period between end-of-life decision and death.
• Emotional exhaustion of ICU nurses and physicians (Maslach Burnout Inventory)
• Perception of work environment by ICU staff in the context of end-of-life practice (validated questionnaire [2])
• Perception of decision-making and EOL Care by relatives after 3 months (validated questionnaire [3])
Anxiety and depression (measured by Brief-Symptom-Inventory 18) of relatives after 3 months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinikum Augsburg; Klinik für Anästhesiologie und Operative Intensivmedizin; Operative Intensivstation; Dr. med. Ulrich Jaschinski, Augsburg**
- Medical Center **Bundeswehrkrankenhaus Berlin; Abt.X, Abteilung für Anästhesie, Intensivmedizin, Notfallmedizin und Rettungsdienst; Interdisziplinäre Intensivstation; OFA Karin Dey, Berlin**
- University Medical Center **Charité Universitätsmedizin Berlin; Klinik für Anästhesiologie mit Schwerpunkt operative Intensivmedizin CCM/CVK; Station 8i; Univ.-Prof. Dr. med. Claudia Spies, Berlin**
- University Medical Center **Charité Universitätsmedizin Berlin; Klinik für Anästhesiologie mit Schwerpunkt operative Intensivmedizin CCM/CVK; Interdisziplinäre NeuroIntensivstation 1; Dr. med. Katrin Schmidt, Berlin**
- University Medical Center **Universitätsklinikum Carl Gustav Carus Dresden; Klinik und Poliklinik für Anästhesiologie und Intensivtherapie; Intensivtherapiestation Haus 58; Prof. Dr. med. Max Ragaller, Dresden**
- Medical Center **Krankenhaus Düren; Klinik für Anästhesiologie, operative Intensivmedizin, Notfallmedizin und Schmerztherapie; Operative Intensivstation; Prof. Dr. Stefan Schröder, Düren**
- Medical Center **Universitätsklinikum Jena; Klinik für Anästhesiologie und Intensivmedizin; Intensivstation I / II; PD Dr. med. Christiane Hartog, Jena**
- University Medical Center **Universitätsklinikum Leipzig; Klinik und Poliklinik für Anästhesiologie und Intensivtherapie; Interdisziplinäre Operative Intensivstation (IOI); PD Dr. med.habil. Sven Bercker, Leipzig**
- University Medical Center **Klinikum der Universität München; Klinik für Anästhesiologie; Anästhesiologische Intensivstation; Univ.-Prof. Dr. med. Josef Briegel, München**
- Medical Center **Klinikum Vest, Recklinghausen; Zentrum für Anästhesiologie, Intensivmedizin und Schmerztherapie: Interdisziplinäre Intensivstation; Prof. Dr.med. Hans-Georg Bone, Recklinghausen**
- University Medical Center **Universitätsklinikum Ulm; Klinik für Anästhesiologie; Anästhesiologische Intensivstation G1; Prof. Dr. med. Manfred Weiss, Ulm**
- Medical Center **Klinik Tettnang; Klinik für Anästhesiologie, Intensivmedizin, Notfallmedizin und Schmerztherapie; Intensivstation; Dr. med. Andrej Michalsen, M.P.H. , Tettnang**
- University Medical Center **Universitätsklinikum Tübingen; Medizinische Klinik; Internistische Intensivstation 93; Prof. Dr. med. Reimer Riessen, Tübingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/15**
- Target Sample Size: **970**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**

Gender: **Both, male and female**

Minimum Age: **18 Years**

- Maximum Age: **no maximum age**

Additional Inclusion Criteria

All patients who die or who had a limitation of life-sustaining interventions in the ICU

Exclusion criteria

Patients without limitation of life sustaining therapy who are discharged alive; patients on intermediate care or step down units or normal wards

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Telephone: **[---]***

Institutional budget, no external funding (budget of sponsor/PI)

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Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.uniklinikum-jena.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/09/30**

Trial Publications, Results and other documents

- Background literature **1.** **Sprung CL, Cohen SL, Sjokvist P, et al. End-of-life practices in European intensive care units: the Ethicus Study. JAMA 2003; 290: 790-7**
- Background literature **2.** **Azoulay E, Pochard F, Kentish-Barnes N, et al. Risk of post-traumatic stress symptoms in family members of intensive care unit patients. Am J Respir Crit Care Med 2005; 171: 987-94**
- Background literature **3.** **Hartog CS, Schwarzkopf D, Riedemann NC, et al. End-of-life care in the intensive care unit: A patient-based questionnaire of intensive care unit staff perception and relatives' psychological response. Palliat Med 2015; 29: 336-45**
- Background literature **4.** **Azoulay E, Herridge M. Understanding ICU staff burnout: the show must go on. Am J Respir Crit Care Med 2011; 184: 1099-100**
- Background literature **5.** **Schwarzkopf D, Westermann I, Skupin H, et al. A novel questionnaire to measure staff perception of end-of-life decision making in the intensive care unit-Development and psychometric testing. J Crit Care 2015; 30: 187-95**
- Background literature **6.** **Aiken LH, Sermeus W, Van den Heede K, et al. Patient safety, satisfaction, and quality of hospital care: cross sectional surveys of nurses and patients in 12 countries in Europe and the United States. BMJ 2012; 344: e1717**
- Background literature **7.** **Zander B, Dobler L, Busse R. [Study assesses causes of burnout. Psychological illnesses are disproportionately frequent in the nursing field]. Pflege Zeitschrift 2011; 64: 98-101**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*